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# The Effects of a Standardized Patient Education Program on Self-Management Outcomes in Patients with HIV

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# Standardized Education and HIV Self-Management Outcomes A Pilot Study

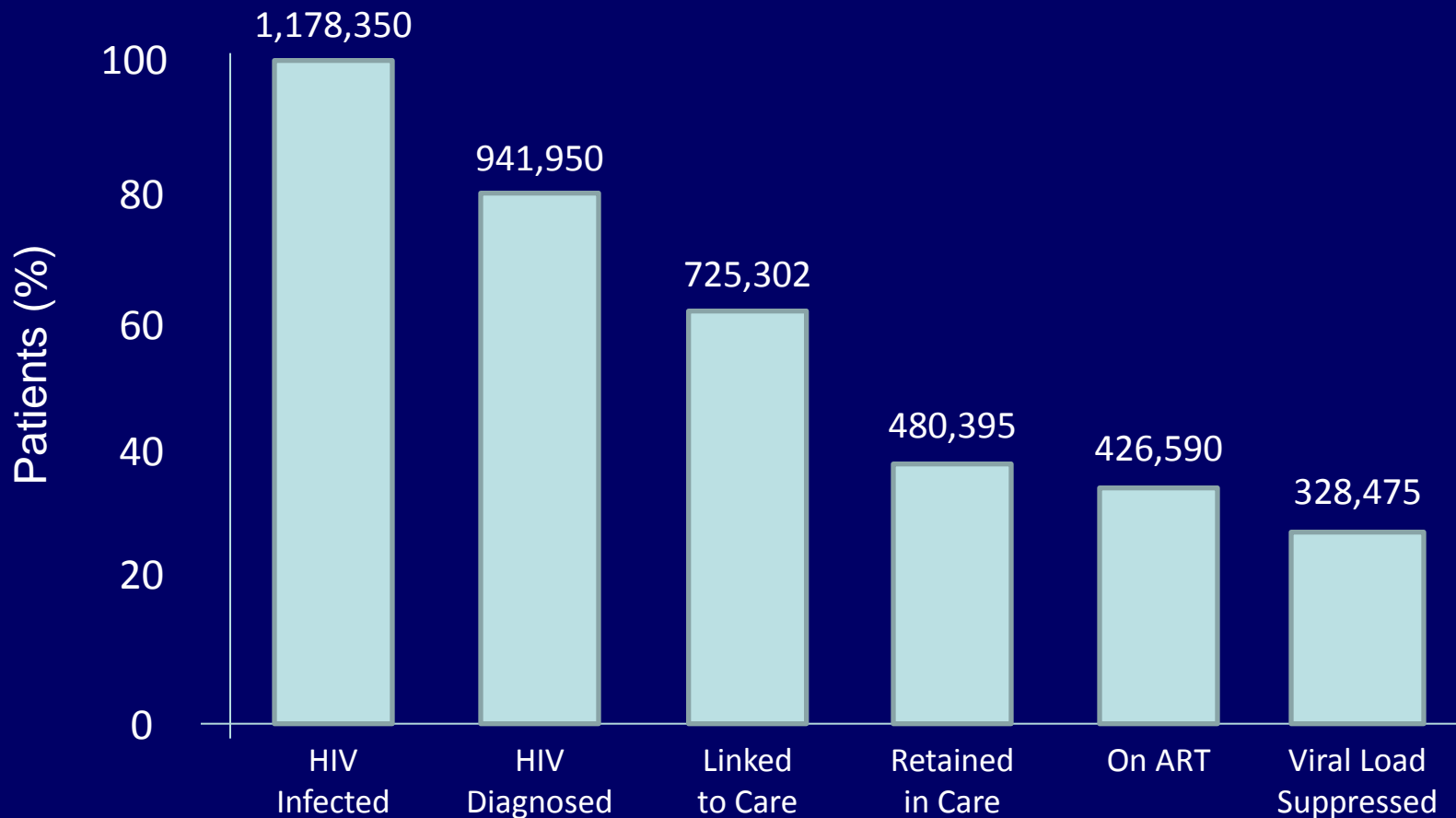
Jason J. Schafer  
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# Background

- HIV has increasingly become recognized as a chronic disease with advances in treatment
- To receive benefits of current HIV treatments, patients must be adherent to care
  - Three main components
    - Medication compliance, attendance at provider appointments, completion of laboratory work
    - Each has been associated with a decrease in HIV-related morbidity, mortality and healthcare costs

# Background

Number of US patients engaged in the continuum of HIV Care



# Background

## Potential Barriers to HIV Care

- Barriers for entry into care
  - Finances
  - Transportation
  - Substance abuse
  - Fear of people knowing and stigma
  - Fear of HIV medication side effects
  - HIV knowledge
- Barriers to adherence to care (retention)
  - Not well defined

# Rationale

- HIV management is life-long and any strategy for improving adherence must be sustainable
- HIV self-management programs can improve adherence to care
  - The Positive Self-Management Program (PSMP)
    - Improved adherence through patient empowerment
    - Time intensive and impractical (14 hours over seven weeks)
- There is a need for a brief but thorough program that can be delivered within the confines of one clinic visit

# Research Question and Objectives

- Can a short, standardized HIV education program delivered during a provider visit improve patient self-management of HIV measured by adherence to care as well as increase patient knowledge of their disease state?
- Primary objective: To evaluate how a brief, standardized education program impacts patient adherence to medications, completion of lab work, and attendance at office visits
- Secondary objective: To examine how a patient's knowledge of his or her disease state changes over the course of the study compared with baseline

# Methods

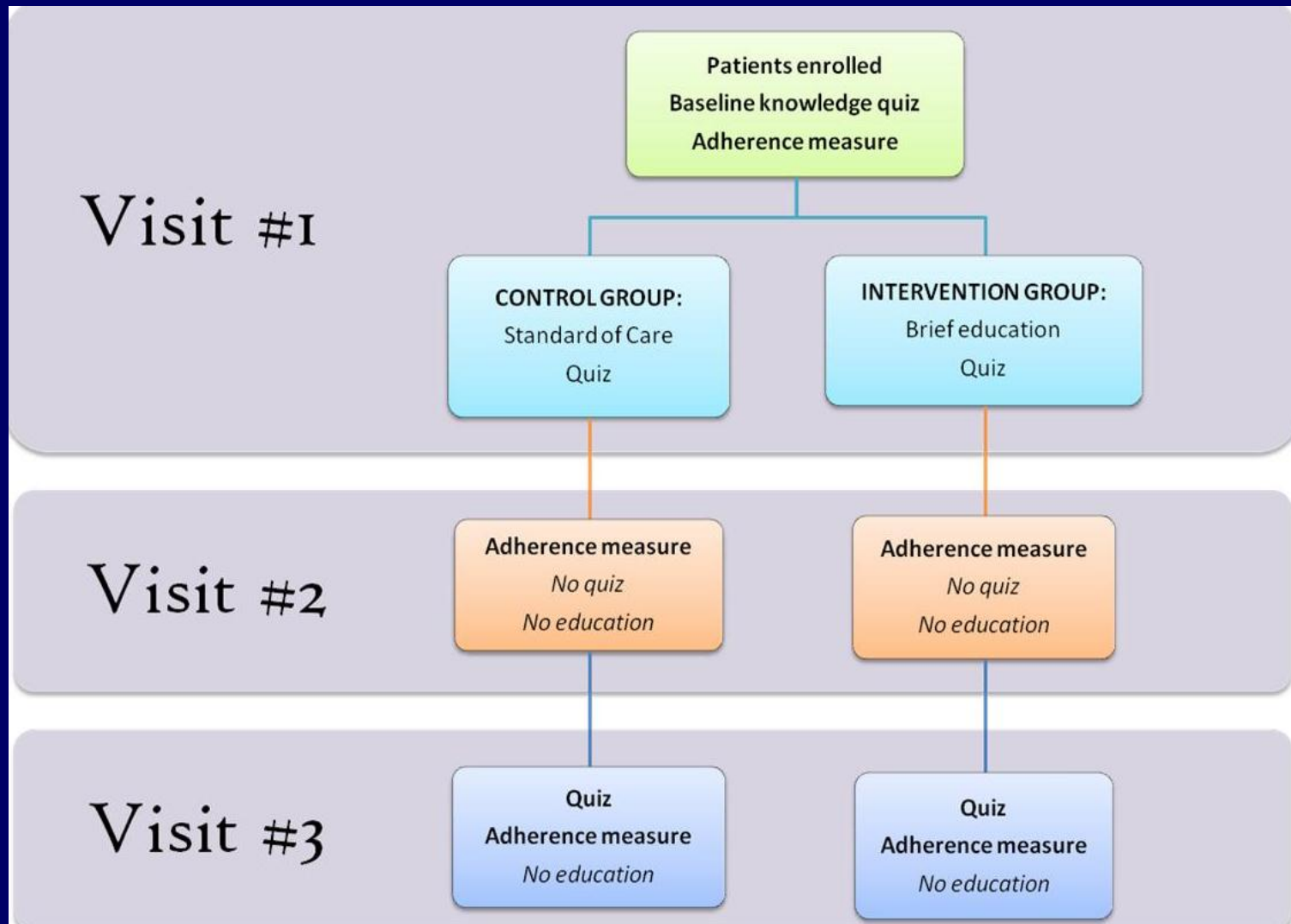
- Pilot Study
  - This program was initially implemented as a pilot study to a sample of patients
  - The completed pilot will be used to determine:
    - If enrollment should be expanded beyond the pilot to achieve statistical power
    - If the program should be targeted to certain clinic patients that might receive the greatest benefit from participating



# Methods

- Subjects are randomized to a standard visit (control) or a standard visit plus a 10 minute scripted educational session (intervention)
- Baseline knowledge and adherence are measured using validated tools
- The intervention is an educational presentation by the investigator using an illustrated booklet
- Participants receiving education retake the quiz following the intervention to assess learning
- Adherence is followed over the next 2 scheduled interactions. All participants repeat the initial quiz during the final visit to assess change in knowledge

# Methods



# Baseline and Post-Intervention Data Analysis

- Enrollment of the pilot study population has been completed (n=45) and a baseline data analysis performed
- T-tests and Chi-square tests were used to detect differences in baseline characteristics between groups
- Testing was also performed to identify characteristics potentially associated with perfect baseline adherence
- Post-interventional analyses were performed to evaluate:
  - Changes in HIV knowledge from baseline for the intervention group
  - Changes in adherence to care for the intervention and control groups

# Baseline Data Analysis

## Demographics and Baseline Characteristics

Variables	Intervention (n=24)	Control (n=21)	P-value
<b>Demographics</b>			
Male gender	18 (75%)	16 (76%)	0.138
African American	19 (79%)	12 (58%)	0.256
Mean age (years)	47	47	1.000
Mean time since HIV diagnosis (yrs)	9.75	10.75	0.108
Mean time in the practice (yrs)	5.5	6	0.574
Mean CD4 count (cells/mm <sup>3</sup> )	484	471	0.195
Mean nadir CD4 count (cells/mm <sup>3</sup> )	186	98	0.013
Current viral load detectable	9 (38%)	7 (33%)	0.771
Mean number of comorbid conditions	1.9	2.1	0.706
Mean number of other meds	2.8	2.5	0.961
<b>ART History</b>			
Mean duration of current regimen (yrs)	2.9	4.1	0.327
Multiple tablets in current regimen	15 (63%)	16 (76%)	0.322
Previous ART failure	9 (38%)	3 (15%)	0.079
Has received >1 ART regimen	10 (42%)	11 (52%)	0.472
<b>Baseline Adherence</b>			
Perfect overall adherence	7 (29%)	7 (33%)	0.763
Perfect medication adherence	20 (83%)	14 (67%)	0.194
Perfect appointment adherence	8 (33%)	10 (48%)	0.329
Perfect laboratory adherence	9 (38%)	10 (48%)	0.493
<b>Baseline Knowledge of HIV Infection</b>			
Perfect HIV knowledge	5 (25%)	9 (48%)	0.114

# Baseline Data Analysis

## Assessment of Patient Characteristics for Possible Associations with Adherence to Care at Baseline

Variables	Entire Study Population (n = 45)		P-value
	Perfect Adherence	Non-Perfect Adherence	
Demographics			
Male gender	12	22	0.287
African American	7	24	0.047
Mean age (years)	50	46	0.891
Mean time since HIV diagnosis (yrs)	8.2	11.1	0.841
Mean time in the practice (yrs)	5.8	5.6	0.606
Mean CD4 count (cells/mm <sup>3</sup> )	568	437	0.880
Mean nadir CD4 count (cells/mm <sup>3</sup> )	217	113	0.003
Current viral load detectable	5	9	0.998
Mean number of comorbidities	2	2	1.000
Mean number of other meds	2.5	2.75	0.865
ART History			
Mean duration of current regimen	4.5	3	0.477
Multiple tabs in current regimen	4	10	0.195
Previous ART failure	2	12	0.198
Has received >1 ART regimen	5	9	0.322
Baseline Knowledge of HIV Infection			
Non-perfect HIV knowledge	8	23	0.042

# Post-Intervention Analysis

## Post-Intervention Knowledge and Adherence at Study Visit Two

- Post-intervention knowledge

Variables	Baseline	Post Intervention	P-value
<b>Knowledge in the Intervention Group (n = 24)</b>			
Perfect HIV Knowledge	5 (25%)	16 (67%)	0.002

- Adherence at study visit two

Variables	Intervention (n=24)	Control (n=21)	P-value
<b>Adherence at Visit Two</b>			
Perfect overall adherence	17 (67%)	5 (24%)	0.002
Perfect medication adherence	19 (83%)	12 (67%)	0.111
Perfect appointment adherence	19 (33%)	11 (48%)	0.057
Perfect laboratory adherence	20 (38%)	11 (48%)	0.025

# Post-Intervention Analysis

## A Closer Look at Adherence at Baseline and Study Visit Two

- Baseline adherence

Variables	Intervention (n=24)	Control (n=21)	P-value
<b>Baseline Adherence</b>			
Perfect overall adherence	7 (29%)	7 (33%)	0.763
Perfect medication adherence	20 (83%)	14 (67%)	0.194
Perfect appointment adherence	8 (33%)	10 (48%)	0.329
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- Adherence at study visit two

Variables	Intervention (n=24)	Control (n=21)	P-value
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Perfect laboratory adherence	20 (83%)	11 (52%)	0.025

# Summary and Future Directions

- Adherence to care improves outcomes for patients with HIV infection
  - Less than 50% of HIV patients in the US have consistent care
- Determinants of adherence to care are numerous and patient specific
  - Basic knowledge of HIV infection may be influential
- Initiatives to improve adherence and knowledge are often cumbersome and impractical
  - An efficient but thorough program delivered during a clinic visit that can improve adherence to care is needed



# Summary and Future Directions

- Preliminary results from this pilot study have identified HIV knowledge as a factor possibly linked to adherence
- The delivery of a brief education session during a standard of care clinic visit may have improved:
  - HIV knowledge in the short term
  - Adherence to care at a subsequent visit
- Questions remain:
  - Does improving HIV knowledge truly impact adherence to care?
  - Can this intervention lead to long term HIV knowledge retention?
  - Will this intervention lead to long term retention in HIV care?

# Summary and Future Directions

- Study completion and final analysis
  - 15/45 have completed the final study visit
  - Upon completion, statistical testing will evaluate the overall impact of the intervention
- Results will be presented to clinic physicians and staff
- Investigators and clinic physicians will determine the utility of expanding enrollment beyond the pilot study to achieve statistical power

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